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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,401	01/16/2002	Alfred Pollak	7126-2	8318

35743 7590 12/28/2004

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EXAMINER

JONES, DAMERON L

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,401	Applicant(s) POLLAK ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-46 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24-31, 33-42, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 9/20/04 wherein claims 7, 9, 10, 16, 22, 33, and 34 are amended; claim 32 is canceled; and claims 45 and 46 are added.

Note: Claims 1-31 and 33-46 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 9/20/04 to the rejection of claims 1-31 and 33-42 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First and Second Paragraph Rejections

I. All 112 rejections (first and second paragraph) are withdrawn EXCEPT those over claims 26, 27, and 33.

The rejection of claims 26, 27, and 33 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 6/17/04 and those set forth below.

Applicant asserts that the phrase 'disease, disorder or abnormal physical state' includes oncological, neurological, inflammatory, infection, and degenerative diseases, as well as any other diseases, disorders, or abnormal physical states that would be apparent to one of ordinary skill in the art. For support of such position, Applicant cites page 6, lines 15-22 and page 16, lines 16-20 of the specification.

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Review of pages 6 and 16 of the specification do not set forth what specific conditions that Applicant is intending to be compatible with the instant invention. The claims need to be clear and concise in order for one to ascertain what disease, disorders, or abnormal physical states Applicant is referring to. In addition, in Applicant's response, it is noted that Applicant states that the claim reads on oncological, neurological, inflammatory, infection, degenerative diseases, as well as any other diseases, disorders, or abnormal physical states without listing any disease/disorders/abnormal physical states or classes of disease/disorders/abnormal physical states that may be detected.

II. The rejection of claims 26, 27, and 33 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 6/17/04 and those set forth below.

Applicant assertions are the same as for the 112, first paragraph, rejection above.

The Examiner position is still that the claims are ambiguous because one cannot ascertain what disease, disorder, abnormal physical state, oncological, neurological, inflammatory, infection, degenerative disease, and other diseases, disorders, and abnormal physical states that Applicant is referring to even after reviewing the suggested areas of the specification.

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WITHDRAWN CLAIMS

3. Claims 43 and 44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

NEW GROUNDS OF REJECTIONS

103 Rejections

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-22, 24-31, 33-42, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma (US Patent No. 6,027,711).

Sharma discloses metalloconstructs and applications thereof. The metalloconstructs may be a peptide useful for biological, therapeutic, diagnostic imaging, radiotherapy, or for use in a library or combinatorial chemistry method (see entire document, especially, abstract). The metalloconstructs comprise a metal ion binding backbone for complexing with a metal ion and a biological function domain and optionally, a metal ion. The metal ion binding backbone (support) may be construct of amino acids or have available atoms such as sulfur (column 10, lines 6-27). The biological function domain may constitute a ligand capable of forming a member of a ligand and receptor pair (column 10, lines 45-52; column 11, lines 26-35; column 24,

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lines 35-68). The metal ion may be iron, cobalt, nickel, copper, zinc, manganese, technetium, silver, cadmium, gold, rhenium, or mercury, to name a few ions (column 10, lines 53-57; column 23, line 60 through column 24, line 24). The peptides may be RGD receptor mimics which contain a metal ion binding backbone including two or more contiguous amino acids which are available for complexing with a metal ion and a biological function domain specific for receptors to the tripeptide sequence Arg-Gly-Asp (column 12, line 55 through column 13, line 61; column 19, lines 58-65). The peptides may have the metal ion binding backbone complexed with a gamma emitting metal ion and may be used for imaging thrombosis, cancer, sites of inflammation, or atherosclerotic plaque. In addition, the peptides may also have a metal ion binding backbone that is complexes with a non-radioactive metal ion and may be used as a therapeutic agent for myocardial infarction, thrombosis, restinosis, angiogenesis, bone resorption, or metastatic cancer (columns 13-14, bridging paragraph). The peptide metal ion complexes can transit the brain blood barrier and may be adapted for use in treating or diagnosing conditions of the brain (column 20, lines 35-38). Typically, the products are used for humans, but may be used for other mammals, laboratory, farm, zoo, wildlife, pet, sport, or other animal (column 25, lines 42-50). The biological function domain may be further defined to include a portion of a construct wherein the construct is a peptidomimetic, peptide-like, or metalloconstruct molecule which upon binding of the construct with a metal ion, is biologically active, exhibiting binding to a biological receptor found on cells, tissues, organs or other biological materials (column 25, lines 1-7). Coordinating groups may be present in the peptide chain and may

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include sulfur atoms of thiols. The peptide constructs may be linear or cyclic. The tetradentate peptide construct may be N4, N3S, N2S2, NS3, or any similar combination yielding tetradentate coordination utilizing nitrogen, sulfur, and oxygen atoms (columns 26-27, bridging paragraph). The biological function domain and the metal ion binding backbone are merged so that the biologically relevant functional groups are arranged directly on, and are coextensive, with the metal binding domain, and the binding of the metal ion (columns 29-30, bridging paragraph). Possible ligands include opioid peptides (column 30, lines 14-15). The peptides and method may be used in positron emission tomography and magnetic resonance imaging (column 32, lines 36-44). In column 51, lines 22-40, it is disclosed that depending upon the peptide use, the pH, reducing and buffering agents, and reaction conditions will be altered. Thus, both Sharma and Applicant disclose a composition that may comprise a metal support surface and a conjugate which may comprise a ligand and targeting molecule. In addition, it should be noted that Sharma does not specifically state that the composition may be in kit form.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a composition, kit, and complex comprising a metal support surface and a conjugate comprising a ligand and targeting molecule as set forth in independent claims 1, 35, and 41 because (1) the cited prior art discloses conjugates comprising a ligand and targeting molecule which may be labeled with a metal ion. (2) A skilled practitioner in the art would be motivated to generate a kit for diagnostic and therapeutic purposes comprising the complex/composition because of the ever present

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need for such kits in hospitals, clinics, or other medical facilities. Also, it would have been obvious to one of ordinary skill in the art to use the complexes for SPECT analysis or any other technique because dependent upon the ion selected, various techniques for diagnostic/therapeutic purposes may be utilized.

CLAIM OBJECTIONS

6. Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Note: Claim 23 (in combination with the limitations of all intervening claims) is distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a peptide comprising dimethylglycylserinylcysteinylglycine that is labeled with 99mTc or 188Re.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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December 27, 2004